Informed Patient Choice: A Paradigm Shift in Medical Error and Informed Consent

NIH Inter-Institute Bioethics Group Bethesda, MD May 4, 2009

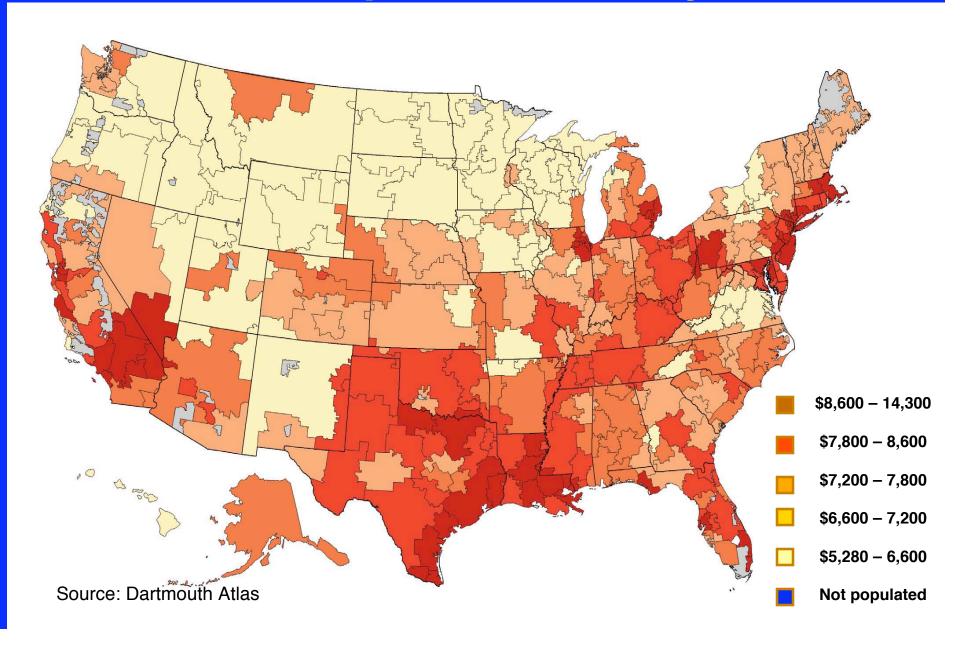
Shannon Brownlee

Visiting Scholar, NIH Clinical Center, Dept. of Bioethics Schwartz Senior Fellow, New America Foundation Overtreated: Why Too Much Medicine is Making Us Sicker and Poorer

DISCLAIMER

- These views are mine alone and do not reflect NIH positions
- No financial conflicts of interest to declare

Medicare \$\$ per Beneficiary 2005



The Three Categories of Care That Show Unwarranted Variation in the U.S.

Effective Care:

Evidence-based care that all with need should receive (aspirin and beta-blockers after AMI)

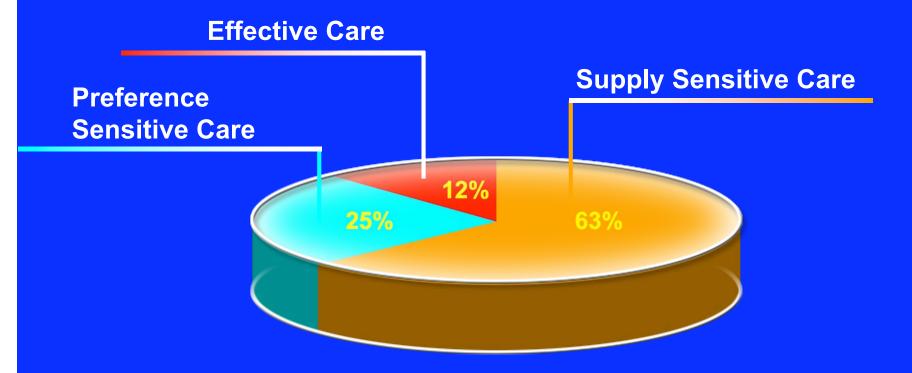
Preference-Sensitive Care:

Elective procedures and tests whose use should depend upon the patient's choice (Mastectomy vs. lumpectomy)

Supply-Sensitive Care:

Discretionary hospitalizations, visits, and procedures

Proportion of Medicare Spending Attributed to Each Category of Unwarranted Variation



Source: John E. Wennberg and Dartmouth Atlas

Preference-Sensitive Care

- Involves tradeoffs -- more than one treatment exists, no treatment is an option, and the outcomes are different
- Decisions should be based on the patient's own preferences
- But provider opinion often determines which treatment is used

Ethical considerations

- Is it ethical to operate on a patient who would have chosen another course of treatment had he or she been fully informed?
- Is it ethical to offer a test outside the context of informed patient choice?

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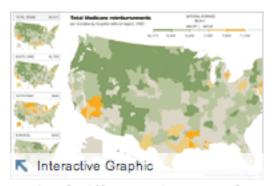
TREATMENTS

Need a Knee Replaced? Check Your ZIP Code.

By STEPHANIE SAUL Published: June 11, 2007

WHY does health care for the average Medicare patient cost nearly twice as much a year in New Jersey, at \$8,076, as it does in Hawaii, at \$4,529?

Multimedia

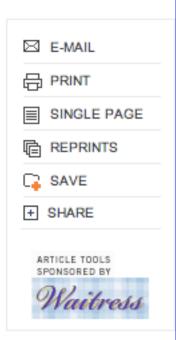


Regional Differences in Cost and Care

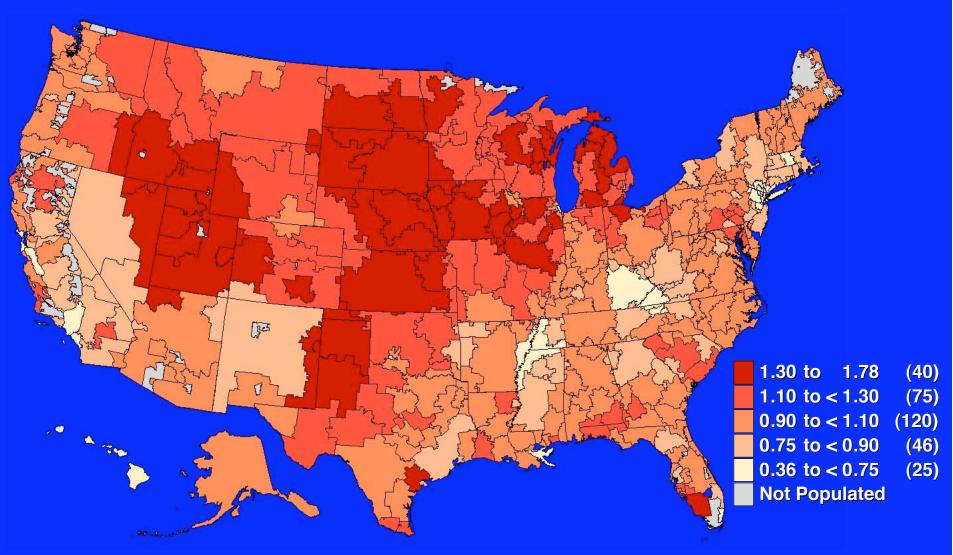
The differences are one example of perplexing geographic variations in medical expenses and quality. And in a study that has important implications for the nation's \$2 trillion health care tab, researchers have found that more

intensive and expensive care does not necessarily mean better outcomes. In fact, the opposite may be true.

The Dartmouth Atlas of Health Care, a research group that studies variations and costs in medical care, sums it up like



Knee Replacement: An Example of Preference-sensitive Care Ratio of knee replacement rates to the U.S. average (2002-03)



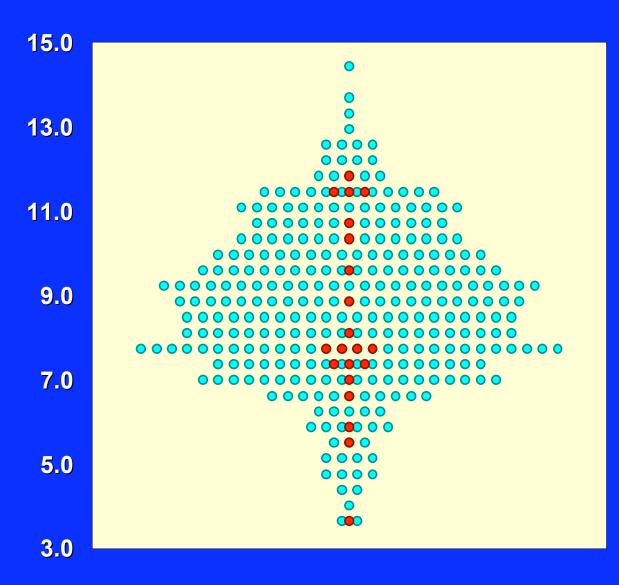
Source: Dartmouth Atlas

The high price of uncertainty



"Well, Bob, it looks like a paper cut, but just to be sure let's do lots of tests."

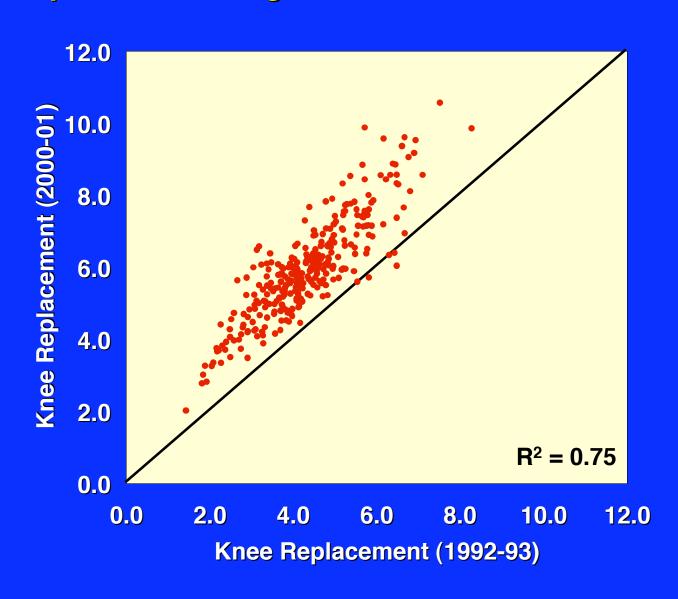
Knee replacement per 1,000 Medicare enrollees (2005)



| HRR | lowest |
|------------------------|--------|
| Lubbock, TX | 3.15 |
| Salt Lake City, UT | 3.13 |
| Bismarck, ND | 3.13 |
| St. Paul, MN | 3.12 |
| Minneapolis, MN | 2.92 |
| Casper, WY | 2.74 |
| Baltimore, MD | 2.56 |
| Wilmington, DE | 2.36 |
| Washington, DC | 2.16 |
| Richmond, VA | 2.13 |
| Bangor, ME | 2.09 |
| Lebanon, NH | 2.08 |
| Baton Rouge, LA | 2.05 |
| Portland, ME | 1.99 |
| Seattle, WA | 1.98 |
| Burlington, VT | 1.93 |
| Hartford, CT | 1.83 |
| Worcester, MA | 1.81 |
| Providence, RI | 1.55 |
| White Plains, NY | 1.47 |
| Manhattan, NY | 1.00 |
| | |

Ratio to

Relationship Between Knee Replacement Rates among hospital referral regions in 1992-93 and 2000-01



Conditions involving preference-sensitive surgical decisions

Condition

- Silent gall stones
- Chronic stable angina
- Hip and knee arthritis
- Carotid artery stenosis
- Herniated disc
- Early prostate cancer
- Enlarged prostate
- Middle-aged male
- Early Breast cancer

Treatment Options

Surgery versus watchful waiting

PCI vs. surgery vs. other methods

Joint replacement vs. pain meds

Surgery vs. aspirin

Back surgery vs. other strategies

Surgery vs. radiation vs. waiting

Surgery vs. other strategies

PSA test versus no test

Mastectomy vs. lumpectomy

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Determining the Need for Hip and Knee Arthroplasty: The Role of Clinical Severity and Patients' Preferences

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BACKGROUND. Area variation in the use of surgical interventions such as arthroplasty is viewed as concerning and inappropriate.

OBJECTIVES. To determine whether area arthroplasty rates reflect patient-related demand factors, we estimated the need for and the willingness to undergo arthroplasty in a high-and a low-use area of Ontario, Canada.

Research Design. Population-based mail and telephone survey.

for surgery, and evidence of arthritis on examination and radiographs. Estimates of need were then adjusted for patients' willingness to undergo arthroplasty.

RESULTS. Response rates were 72.0% for questionnaires and interviews. The potential need for arthroplasty was 36.3/1,000 respondents in the high-rate area compared with 28.5/1,000 in the low-rate area (P < 0.0001). Among individuals with potential need, only

Determining the Need for Hip and Knee Arthroplasty: The Role of Clinical Severity and Patients' Preferences

• . . . Among those with severe arthritis, no more than 15% were definitely willing to undergo (joint replacement), emphasizing the importance of considering both patients' preference and surgical indications in evaluating need and appropriateness of rates of surgery

Papers

Decision aids for patients facing health treatment or screening decisions: systematic review

Annette M O'Connor, Alaa Rostom, Valerie Fiset, Jacqueline Tetroe, Vikki Entwistle, Hilary Llewellyn-Thomas, Margaret Holmes-Rovner, Michael Barry, Jean Jones

Abstract

Objective To conduct a systematic review of randomised trials of patient decision aids in improving decision making and outcomes. Design We included randomised trials of interventions providing structured, detailed, and specific information on treatment or screening options and outcomes to aid decision making. Two reviewers independently screened and extracted data on several evaluation criteria. Results were pooled by using weighted mean differences and relative risks. **Results** 17 studies met the inclusion criteria. Compared with the controls, decision aids produced higher knowledge scores (weighted mean difference = 19/100, 95% confidence interval 14 to 25); lower decisional conflict scores (weighted mean difference = -0.3/5, -0.4 to -0.1); more active natient participation in decision making (relative risk

tioners. Their efficacy has been described in general reports and reviews.⁴⁻⁶ We conducted a systematic overview of the trials of decision aids to determine whether they improved decision making and outcomes for patients facing treatment or screening decisions.

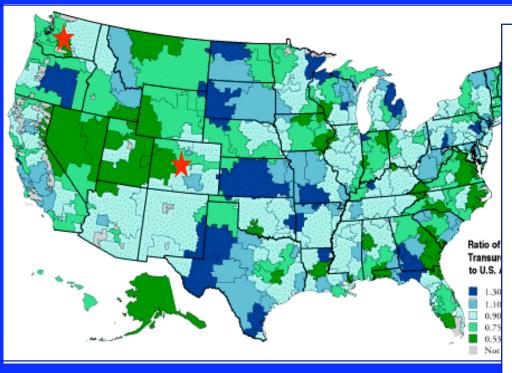
Methods

The search strategy is described in detail elsewhere. We searched the following electronic databases: Medline (1966-April 98); Embase (1980-November 98); PsycINFO (1979-March 98); CINAHL (1983-February 98); Aidsline (1980-98); CancerLit (1983-April 98); and the Cochrane Controlled Trials Register (1998, Issue 4). Additional studies were searched for in our personal files and the contents lists of Health Expectations (1998), Medical Decision Making (January-March 1986-January-March 1998), and Patient Education and

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Sisters of Charity of Ottawa Health Services, Ottawa, Ontario, Canada Valerie Fiset

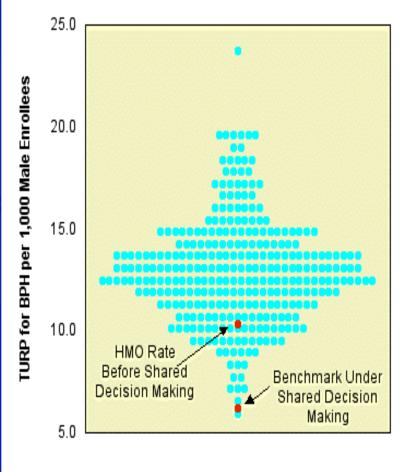
Which rate is right? Impact of improved decision quality on surgery rates: BPH



Knowledge of relevant treatment options and outcomes

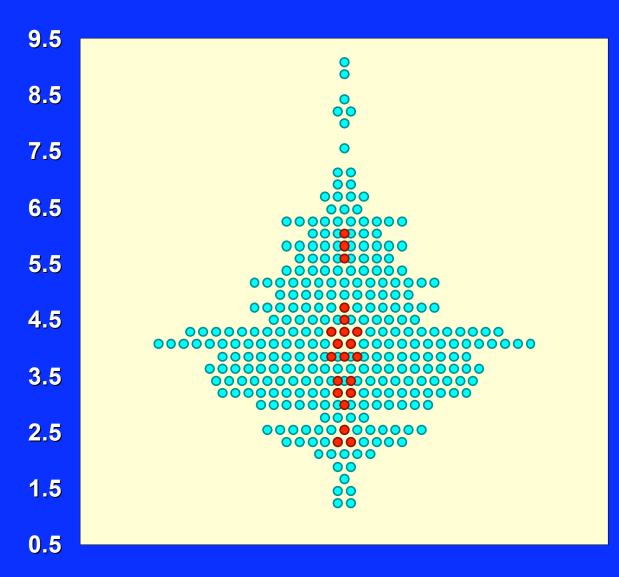
Concordance between patient values and care received





Source: John E. Wennberg

TURP for BPH per 1,000 male Medicare enrollees (2005)



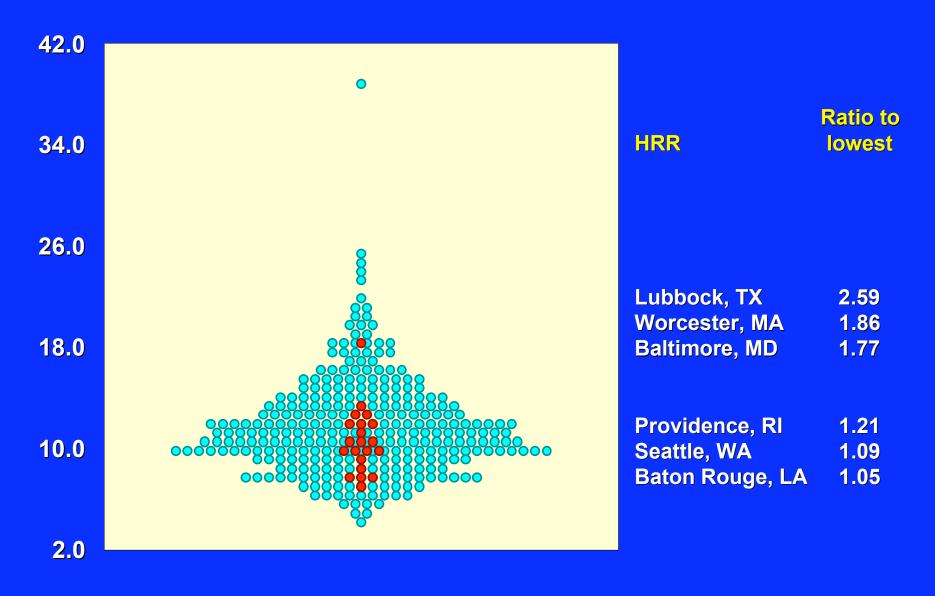
| HRR | lowest |
|-----------------------|--------|
| Providence, RI | 2.67 |
| Lubbock, TX | 2.63 |
| Bismarck, ND | 2.46 |
| Washington, DC | 2.07 |
| Burlington, VT | 2.05 |
| Hartford, CT | 1.92 |
| St. Paul, MN | 1.89 |
| Worcester, MA | 1.89 |
| Baltimore, MD | 1.85 |
| Minneapolis, MN | 1.79 |
| White Plains, NY | 1.74 |
| Bangor, ME | 1.74 |
| Manhattan, NY | 1.74 |
| Portland, ME | 1.57 |
| Seattle, WA | 1.48 |
| Salt Lake City, UT | 1.44 |
| Casper, WY | 1.43 |
| Wilmington, DE | 1.36 |
| Richmond, VA | 1.17 |
| Baton Rouge, LA | 1.03 |
| Lebanon, NH | 1.00 |

Ratio to

CABG surgery per 1,000 Medicare enrollees (2005)



Percutaneous coronary intervention per 1,000 Medicare enrollees (2005)



Back surgery per 1,000 Medicare enrollees (2005)



Bottom Line Implications for Clinical Practice

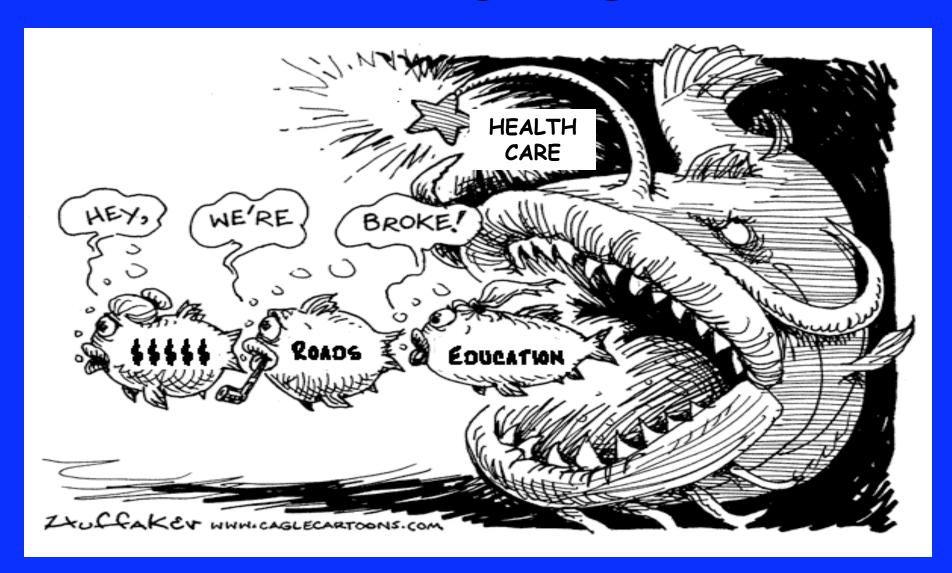
Clinical appropriateness should be based on sound evaluation of treatment options (outcomes research)

Medical necessity should be based on Informed Patient Choice among clinically appropriate options (high quality shared decision-making)

A new way of thinking about medical error?

- Surgery is a major, and potentially dangerous event in a patient's life.
- Operating on a patient who would have chosen another course of treatment is a wrong-patient error.
- Is it unethical to deliver a PSA test outside the context of shared decision making?

Busting budgets



POLICY IMPLICATIONS:

- 1. Clinical effectiveness research won't be enough to bend the cost curve down.
- 2. Patient centered care: Even when we know what works, patients still need to choose what's right for them.
- 3. Unnecessary (or unwanted) treatment poses risk without benefit.
- 4. Ensuring informed patient choice should be a goal of both public policy and clinical practice.

